

# Conventional Versus Invaginated Stripping of the Great Saphenous Vein: A Randomized, Double-Blind, Controlled Clinical Trial

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## Abstract

**Background** An invaginated strip of the great saphenous vein (GSV) may be associated with diminished blood loss and less discomfort compared to conventional stripping in patients with unilateral primary GSV varicosis.

**Methods** Ninety-two patients were randomized for conventional (CON) or invaginated (INVAG) stripping and were followed for 26 weeks postoperatively.

**Results** Both groups ( $n = 46$ ) were well balanced for age, gender distribution, and body mass index. The CON group lost twice as much blood compared to the INVAG group (CON:  $28 \pm 4$  g, INVAG:  $15 \pm 2$  g,  $p < 0.001$ ). Infragenual incision length following a conventional strip was twice as long (CON:  $16 \pm 1$  mm, INVAG:  $8 \pm 1$  mm,  $p < 0.001$ ). Pain as measured with a visual analog scale (minimal 0, max 10) decreased in both groups in a similar fashion from  $3.2 \pm 0.3$  preoperatively to  $0.6 \pm 0.2$  after 26 weeks ( $p < 0.001$ ). Saphenous nerve damage after one month was observed in four CON patients compared to no patients following invagination. Return to work was not different (CON:  $13 \pm 2$  days, INVAG:  $11 \pm 2$  days).

**Conclusion** Invagination of the GSV in uncomplicated primary varicosis may be associated with less surgical trauma compared to a conventional stripping technique.

Surgery is preferred over conservative treatment in symptomatic primary varicosis of the great saphenous vein (GSV) [1]. Although minimally invasive techniques, including endovenous laser ablation, cryotherapy, heat-mediated obliteration, and ultrasound-guided sclerotherapy, have obvious benefits [2–5], Babcock's crosssection and stripping is still considered the standard of care in this patient population [6–8].

Various studies have contributed to optimizing the procedural aspects of insufficient GSV stripping. For instance, removal of the upper-leg GSV portion exclusively (short strip) as opposed to a total-leg GSV strip and pulling a disconnected GSV from groin to knee (and not from knee to groin) both minimize saphenous nerve damage [9, 10]. Although consensus on the concept of groin-to-infragenual GSV strip seems to exist among most surgeons, the optimal method of vein removal is still under debate. Many advocate a conventional approach using a classic acorn tip mounted on the stripper [7, 8], whereas others favor an invaginated procedure [11]. The latter technique is attractive in theory because the vein's adjacent tissue, including nerves and lymphatics, may sustain less collateral trauma. Attenuated blood loss and diminished pain may subsequently occur following such invaginated stripping. However, results of two randomized trials do not favor any of the two approaches and provide somewhat conflicting data [12, 13].

The aim of the present study was to investigate whether an invaginated strip of the GSV was associated with

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diminished blood loss and associated discomfort compared to conventional stripping in patients with unilateral primary GSV varicosis.

## Patients and methods

### General

Yearly about 500 patients undergo varicose surgery in the Maxima Medical Center in Veldhoven, The Netherlands. Patients were enrolled between April 2002 and April 2005 and were studied for 6 months. Patients were eligible for study only if they met all criteria as listed in Table 1. Each patient with a typical history of symptomatic unilateral varicosis underwent physical examination and Duplex ultrasound scanning. If greater than 0.5 s of reverse flow with the patient standing was present in (portions of) the GSV (reflux), study specifics were explained to the patient. All patients were included by the senior surgeon, and they were all classified according to the advanced CEAP consensus (C, clinical; E, etiologic; A, anatomical; P, pathophysiologic) as C<sub>1, 2</sub>, E<sub>p</sub>, A<sub>s</sub>, P<sub>r</sub> (C<sub>1, 2</sub> = telangiectasies, reticular or varicose veins without edema (C<sub>3</sub>), skin changes (C<sub>4</sub>), or ulcers (C<sub>5,6</sub>); E<sub>p</sub> = primary etiology; A<sub>s</sub> = superficial veins, P<sub>r</sub> = reflux) [14].

Before surgery pain was measured using a visual analog scale (VAS). All patients indicated their level of pain themselves using a pencil on a horizontal axis ranging from absence of pain (minimal, VAS = 0) to excruciating (maximal, VAS = 10). A second pain scale, the verbal

rating scale (VRS), was also used (no pain = 0, bearable = 2, unpleasant = 4, strong = 6, terrible = 8, unbearable = 10). All medication was tabulated. If results of a standard laboratory panel were normal, a consent form was signed and the patient was randomized to one of two surgical regimens based on a computerized allocation sequence. A numbered envelop containing the operation technique was inserted into the surgical chart. The local ethics committee approved the study protocol.

### Operative procedure

All patients were operated on in day care. They received 2500 IU of fraxiparin subcutaneously as standard deep venous thrombosis prophylaxis 1–2 h before surgery. The type of anesthesia used was left to the discretion of the attending anesthesiologist. The envelope containing the type of operation to be performed was opened by one of the scrub nurses and the operating technique was communicated to the surgeon just prior to skin incision. Dry weight of gauzes was determined in grams. After skin incision the saphenofemoral junction, including side branches, was dissected. Vicryl 2.0 was used to ligate the GSV and its branches. The saphenous vein was subsequently disconnected from the deep venous system and cannulated by the stripper that was retrieved via an infraglenar stab incision about 4 in. below the medial aspect of the knee joint (Dormo-strip, Telic, Barcelona, Spain).

Conventional GSV stripping (CON) was performed according to Babcock [6]. The smallest of three available acorns (9.5-mm diameter) was mounted onto the stripper and the GSV was pulled through a small infraglenar incision. Blood that subsequently accumulated in the subcutaneous upper-leg tunnel was rolled toward the groin using a 10 × 20-cm gauze. Weighed dry gauzes were then used to absorb these small inguinal pools of blood. This procedure was repeated twice within 30 s following the stripping procedure [12]. All bloody gauzes were weighed again and blood loss was calculated by subtraction.

In patients undergoing an invaginated strip (INVAG), a similar stripper was used without an acorn [15]. After disconnection, the GSV was tied to the stripper, and by pulling the stripper toward the foot, the first side branch forces the GSV to invaginate (Fig. 1A). Once retrieved outside the lower leg, the invaginated vein was checked for completeness (Fig. 1B). Length of groin and infraglenar incisions were measured in millimeters. Details of the operation, if any, were noted in the surgical chart. All patients were operated on by 11 different first- and second-year surgical residents. Most of the supervisions (>70%) were performed by the first author.

**Table 1** Inclusion and exclusion criteria of patients undergoing unilateral short saphenous vein stripping by either a conventional or an inverted stripping technique

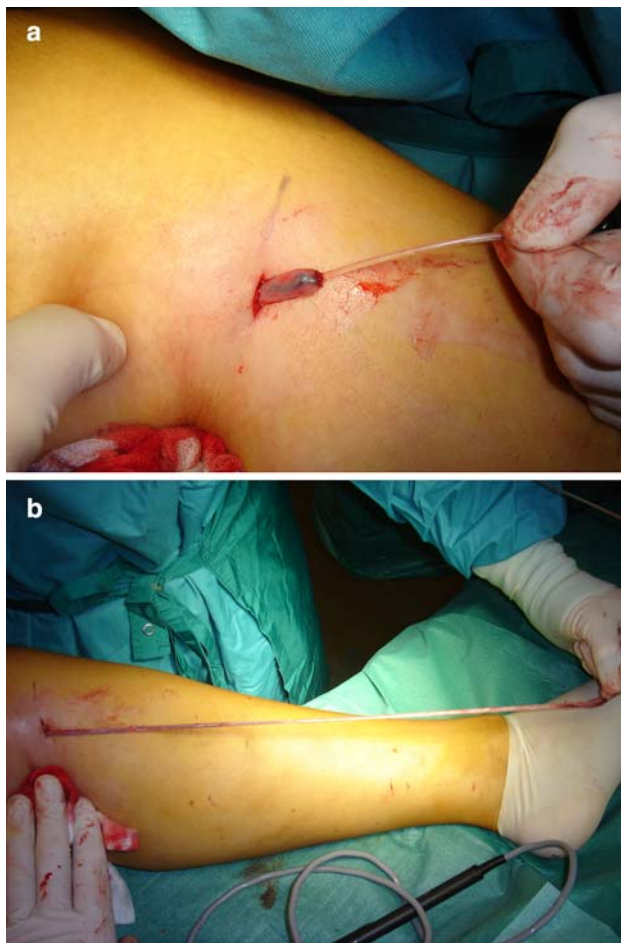
#### Inclusion

Unilateral symptomatic varicosis of GSV  
Insufficiency of (portions of) GSV as determined by duplex ultrasound scanning  
Sufficient deep venous system  
Age > 18 years  
Signed consent  
C<sub>1, 2</sub>, E<sub>p</sub>, A<sub>s</sub>, P<sub>r</sub><sup>a</sup>

#### Exclusion

Previous ipsilateral venous surgery  
SSV insufficiency  
Convolutectomies required  
Previous GSV thrombophlebitis  
Malignancy, renal insufficiency, diabetes mellitus, immunosuppressive medication

<sup>a</sup> CEAP-classification (Clinical-Etiology-Anatomy-Pathophysiology) [14], see text for details



**Fig. 1** **A** Invagination, view at infragenual stab incision. **B** Invagination is complete

#### Postoperative management

Patients received nonadherent compressive lower- and upper-leg dressings (Crepe windsels, Stenstes BV, Oss, The Netherlands) followed on the second postoperative day by grade II compression stockings for 6 weeks (TG-grip, Lohmann/Rauscher, Germany). They were encouraged to resume daily activities from the first postoperative day. Outpatient controls, including pain evaluation, were performed after week 1, week 4, and week 26. Physical examination entailed inspection of groin and infragenual wounds. Altered sensations on the medial aspect of the upper leg (discomfort, pain, dysesthesia, dullness) were tabulated as present or absent. Diminished sensibility on the lower leg reflecting saphenous nerve damage was also tabulated as present or absent. Standard laboratory testing, as was performed preoperatively, was repeated just before discharge, and at 1 and 4 weeks postoperatively. All outpatient evaluations were performed by two dedicated residents (BK, KdK) who were blinded to the type of operation the patient underwent. All patients also remained

ignorant of the operative technique throughout the entire 26-week study period. The final 26-week control was performed by the senior surgeon (MS) who also communicated the operating technique to the patient.

#### Analysis

A power analysis based on a pilot study demonstrating a 30% reduction in blood loss between the conventional and the invaginated group suggested inclusion of 40 patients in each study arm, with a standard  $\alpha$  of 0.05 and  $\beta$  of 0.10. Statistical analysis was performed using the  $\chi^2$  test when comparing discrete variables and the  $t$  test when appropriate. Data are expressed as mean  $\pm$  SEM. A  $p < 0.05$  is considered significant.

#### Results

One hundred ten patients undergoing a short GSV strip as a single procedure presented during the three-year period. Six individuals refused participation, and 12 patients were excluded [surgeon performed convulsectomies ( $n = 8$ ), withdrawal of consent ( $n = 1$ ), recurrent surgery ( $n = 1$ ), thrombophlebitis ( $n = 1$ ), malignancy found during preoperative workup ( $n = 1$ )]. Therefore, the population that was analyzed included 92 patients. Both arms of the study included 46 patients. Follow-up was 100% at one week, 96% at 4 weeks, and 95% at 26 weeks.

Demographics and preoperative characteristics of these 92 patients are given in Table 2. Both groups were well balanced with respect to number, age, gender distribution, body mass index, aspirin medication (stopped 10 days prior to operation), and type of anesthesiology.

There was no mortality or major morbidity. All patients were discharged on the day of the operation as planned. Patients undergoing a conventional GSV procedure lost almost twice as much blood when compared to the invaginated group (CON:  $28 \pm 4$  g, INVAG:  $15 \pm 2$  g,  $p < 0.001$ , Table 3). The length of the infragenual incision in patients undergoing a conventional strip was twice as long compared to the invaginated strip (CON:  $16 \pm 1$  mm, INVAG:  $8 \pm 1$  mm,  $p < 0.001$ ). The mean operation time was 2 min less in the invaginated group, but the difference did not attain significance ( $p = 0.19$ ). Alterations in hemoglobin, hematocrit, thrombocytes, and C-reactive protein over time were not different between both groups.

Complications associated with the procedure were rare and are given in Table 4. Failure to cannulate the vein over its entire length occurred in four patients (CON:  $n = 3$ , INVAG:  $n = 1$ , ns). Total invagination was successful in all patients but one due to rupture at the level of the mid-

**Table 2** Patient characteristics

	Conventional	Invaginated	<i>p</i> value
Number of patients	46	46	
Age (year)	48 ± 2	46 ± 2	n.s
Female/male	43 / 3	40 / 6	n.s
Body mass index (%)	24.4 ± 0.6	24.7 ± 0.6	n.s
Aspirin	1	1	
General/regional anesthesiology	9/37	8/38	n.s.

**Table 3** Intraoperative characteristics of both study populations

	Conventional ( <i>n</i> = 46)	Invaginated ( <i>n</i> = 46)	<i>p</i> value
Blood loss (g)	28 ± 4	15 ± 2	<0.002
Length of incision			
groin (mm)	45 ± 1	45 ± 1	n.s
knee (mm)	16 ± 1	8 ± 1	<0.001
Operating time (min)	26 ± 1	24 ± 1	0.19

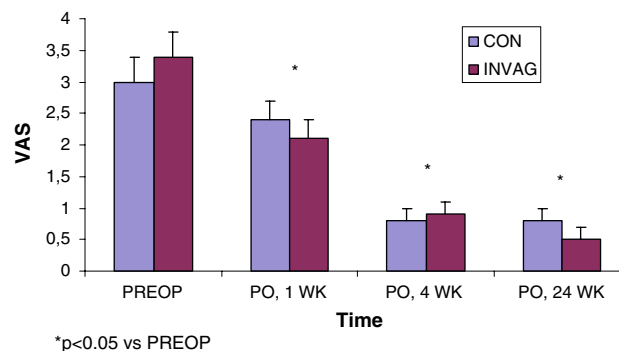
**Table 4** Complications in patients undergoing unilateral stripping

	Conventional ( <i>n</i> = 46)	Invaginated ( <i>n</i> = 46)
Incomplete canulation	3	1
Incomplete inversion	—	1
Delayed healing groin	4	1
Altered sensations upper leg (sore, dull, dysesthesia)		
1 week	15	10
4 weeks	8	7
26 weeks	3	0
Altered sensibility lower leg (saphenous nerve damage)		
1 week	5	2
4 weeks	4	0
26 weeks	1	0

thigh perforator. Delayed healing of the groin (> 1 month) was observed in five patients (CON: *n* = 4, INVAG: *n* = 1). All five responded well to conservative measures. Altered sensations in the upper leg, including pain and/or dullness, was frequently observed in both groups but was usually resolved after 26 weeks (Table 4).

Symptomatology consistent with damage to the saphenous nerve was observed in four CON cases at the first postoperative month control compared to zero patients following invagination. Saphenous nerve damage appeared transient in three but was still present at 26 weeks in one CON patient.

Preoperative pain as measured with a VAS score was similar in both groups (CON: 3.0 ± 0.4, INVAG: 3.4 ± 0.3). Pain levels significantly diminished over time

**Fig. 2** Preoperative and postoperative pain at standard intervals measured by visual analog scale (0: absent, 10: unbearable) in patients undergoing conventional (CON) or invaginating (INVAG) stripping of the greater saphenous vein. \**p* < 0.05 vs preoperative

in both groups in a identical fashion (Fig. 2). VRS testing demonstrated a similar pattern (data not shown). Return to work was not different between the two groups (CON: 13 ± 2 days, INVAG: 11 ± 2 days, ns).

## Discussion

One hundred years of studies on saphenous vein varicosis has left us with some unanswered questions. The issue of neovascularization following groin exploration during GSV surgery is still open to debate. It also remains unclear if side branches of the groin GSV must be ligated in all circumstances. However, some questions appear answered. Surgery is superior to conservative measures in the treatment of uncomplicated varicose veins [1]. Moreover, symptomatic saphenous vein varicosis is effectively treated with saphenofemoral ligation, but more so in combination with removal of a portion of the insufficient GSV [16]. Ideally, a short portion of the GSV is to be pulled out (stripped) from the groin to just below knee level, as this will minimize saphenous nerve damage [9, 10]. However, the best technique of stripping is still uncertain and open to discussion. Many advocate conventional surgery using acorns mounted on a stripper [6, 7], whereas others favor some form of invagination [12, 13, 17].

The concept of vein removal by invagination is attractive. A conventional strip may result in a “thick wrap of vein mounted on an oversized acorn” that is pulled toward the knee while damaging surrounding tissue, including nerves and lymphatics [18, 19]. Vein and acorn are usually removed via an additional infraglenar incision, although a separate tie fixed to the acorn may be used to draw the complex back into the groin wound, thus limiting the length of the infraglenar wound [20]. Invagination proponents have claimed superiority of their technique but studies usually have limited evidence [11, 18, 19, 21–28].



**Table 5** Overview of studies on efficacy of invaginating saphenous veins

Author	Year	Study type	GSV (n)	SSV (n)	Invagination technique	Operation time	Incomplete invagination	Nerve injury	Cosmesis	Pain/bruising	Anesthesiology
Saelens [11]	1992	Retrospective	1300	0	Invagination, over nylon thread	n.m.	n.m.	0.3%	n.m.	0.5%	General/regional/local
Oesch [26]	1993	Prospective	43	40	PIN	Reduced	11/83	0	Excellent	n.m.	Local
Goren [18]	1994	Prospective	91	21	PIN	n.m.	0	0	Maximal	Minimal	Locoregional
Goren [19]	1995	Retrospective	231	40	PIN	n.m.	n.m.	n.m.	Optimal	Minimal	Locoregional
Conrad [25]	1996	Prospective	100	28	PIN	n.m.	15/100	0	Improved	Remarkably painfree	General
Lacroix [12]	1999	Randomized	60	0	Conventional (n = 30) vs. invagination (universal stripper, n = 30)	n.m.	8/30	Similar	15% Similar	Similar	General (?)
Durkin [13]	1999	Randomized	80	0	Conventional (n = 37) vs. PIN (n = 43)	Similar	8/43	Similar	Smaller exit wounds	Similar	General (?)

GSV = great saphenous vein; SSV = small saphenous vein, PIN = perforate invagination; n.m. = not mentioned, ? = not clear

Two randomized trials yielded conflicting results [12, 13]. Interestingly, a frequently used vascular reference book has introduced invagination as the gold standard surgical technique for GSV varicosis, although studies on long-term results are absent [29]. Reports on the efficacy of GSV and SSV (small saphenous vein) invagination are listed in Table 5.

Most studies on invagination suggest that there is attenuated blood loss following inverted stripping. However, volume of blood loss was measured in one study only, and this report indeed demonstrated a 50% reduction in blood loss (conventional 50 ml vs. inverted 25 ml) [30]. Postoperative hematoma surface as a possible reflector of total blood loss was similar in three randomized studies [12, 13, 30]. One study measuring clot formation using a red blood cell labeling technique demonstrated that venous inversion resulted in diminished thigh blood pooling compared to conventional stripping [31]. In the present study it was decided to define intraoperative blood loss as the total amount that was obtained from the groin following three rolling maneuvers at upper-leg level immediately following removal of the stripper as suggested [12]. Patients who underwent conventional stripping lost twice as much blood compared to the invagination patients. Although the clinical significance of a 13-ml difference may seem small, one may argue that diminished intraoperative blood loss reflects attenuated tissue damage following passage of the stripper.

Complications following GSV stripping are usually rare. Indeed, in the present study the number of complications was also minimal. Cannulation of the GSV over its entire length appeared unsuccessful in four patients, three of whom belonged to the conventional group. Prolonged groin wound healing was observed in four conventional patients versus one invagination patient. Several factors may contribute to successful wound healing. Occurrence of groin infection following stripping is largely operator-dependent [32]. Mean length of operation was 2 min less in the invagination group. One may hypothesize that accumulation of blood in the groin, possibly also more common after conventional stripping, may have contributed to delayed healing in some conventional patients.

A possible disadvantage associated with invagination stripping is saphenous vein rupture, usually at the level of the mid-thigh perforator. Percentages of GSV rupture range from 0% to 25% (Table 5). Rupture results in removal of only the GSV part located between the groin and mid-thigh perforator. This unforeseen event occurred only once in the present study (2%). A rupture happens if any portion of the GSV is weaker compared to its strength at the level of the perforator. Depending on the sufficiency of the remaining part of the GSV (as determined by preoperative Duplex scanning), one may accept such a

complication. If removal of remaining parts of the GSV is required, it is advisable to invaginate the remainder of the vein, starting at the infragenua incision and moving toward the groin [22]. Alternatively, one may strip the rest of the GSV using a conventional acorn technique. Patients who have suffered from an ascending thrombophlebitis of the GSV are thought to be at risk for such ruptures [28]. Routine duplex scanning should be aimed at recognizing thickening at the level of the perforator in this patient group. It is probably wise to preoperatively mark these perforators using duplex scanning. After saphenofemoral ligation and GVS disconnection in the groin wound, surgical exploration at the mid-thigh level may allow for ligation of the thickened perforator followed by a second GSV cannulation toward the knee. The GSV is safely removed in two tempi thus avoiding annoying ruptures.

Two separate postoperative pain syndromes need to be distinguished after GSV removal. The first is associated with the surgical trauma experienced after passage of the stripper and may be less following invagination, as suggested in Table 4. The second is caused by saphenous nerve damage. Several studies have expanded our understanding of nerve injury after vein stripping. A short strip has far less risk for nerves compared to a groin-to-ankle strip [9]. Direction of stripping also appears to determine the frequency of nerve injury [10]. The first week control indicated that five patients sustained nerve damage following conventional stripping compared to two patients following invagination. After 1 month, four conventional patients still reported symptoms associated with nerve damage compared to no invagination patients. A similar trend in favor of invagination was observed in other studies [12, 13]. The clinical relevance of saphenous nerve damage is subject to debate. Most studies as well as ours show that symptoms usually disappear in the first postoperative year. One study demonstrated that saphenous nerve damage did not result in any significant morbidity or loss of quality of life after 4.5 years [33]. Nevertheless, saphenous nerve damage following stripping is probably a parameter of surgical damage associated with the operation and should be avoided.

What additional advantages are possibly associated with an invagination technique? Most authors report improved cosmesis following invagination (Table 5). Cosmesis is difficult if not impossible to measure. In the present study the infragenua incision following invagination was only half as long as that in the conventional group (8 vs. 16 mm). A second advantage is the claim that invaginating techniques are also effective and safe in short saphenous vein insufficiency. Not a single case of sural nerve damage was observed following SSV invagination halfway down the calf in 89 patients (Table 5) [18, 25, 26].

In conclusion, invagination of the great saphenous vein is associated with less surgical damage compared to

conventional stripping techniques. Long-term studies investigating frequency of recurrences and neovascularization must be finished before invagination may be claimed as a gold standard technique of GSV removal.

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